

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS**

UNITED STATES OF AMERICA, *et al.*,
ex rel. CIMZNHCA, LLC,

Plaintiff,

v.

UCB, INC.; RXC ACQUISITION
COMPANY d/b/a RX CROSSROADS;
OMNICARE, INC.; and CVS HEALTH
CORPORATION,

Defendants.

Case No. 3:17-CV-765-SMY-MAB

DECLARATION OF COLIN M. HUNTLEY

I, Colin M. Huntley, declare as follows:

1. I am an attorney with the United States Department of Justice, where I currently serve as an Assistant Director in the Fraud Section of the Civil Division. I submit this Declaration in support of the United States' Motion for Reconsideration of the Court's April 15, 2019 Memorandum and Order denying the United States' motion to dismiss the above-captioned matter. I am one of the Department of Justice attorneys assigned to the *qui tam* complaints filed by affiliates of Venari Partners LLC, dba, "National Healthcare Analysis Group" ("NHCA Group Relators"). I have personal knowledge of the matters discussed in this declaration.

2. On or about October 3, 2018, attorneys from the Department of Justice contacted counsel for the NHCA Group Relators to advise them that the United States planned to seek dismissal, pursuant to 31 U.S.C. § 3730(c)(2)(A), of ten *qui tam* complaints they had filed across seven judicial districts.

3. On October 4, 2018, the Department of Justice received a letter from Samuel Baxter, Mark Lanier, and Kenneth Starr, counsel for certain of the NHCA Group Relators. The letter was addressed to Michael Granston, Director of the Fraud Section of the Department of Justice's Civil Division. The letter requested "that the Government defer filing its motion until we have a chance to meet with you to better understand the Government's concerns and discuss steps to address them."

4. In response to relators' request, the Department agreed to defer filing any motions to dismiss. The Department further agreed to discuss the United States' concerns with counsel for the NHCA Group Relators, and a teleconference was scheduled for October 9, 2018.

5. On October 9, 2018, Department of Justice attorneys participated in a teleconference with attorney Marc Mukasey of the law firm Greenberg Traurig, LLP, who participated on behalf of Venari Partners LLC and its investor members. None of the attorneys or law firms who represent the NHCA Group Relators participated in the teleconference. The following Department of Justice attorneys participated in the teleconference with Mr. Mukasey: Michael Raab, Acting Deputy Assistant Attorney General for the Civil Division's Commercial Litigation Branch; Michael Granston; and myself. The teleconference lasted approximately 30 minutes. Consistent with the relators' request of October 4, Mr. Granston enumerated the government's specific concerns, including: (1) whether there is sufficient factual and legal support to prove violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (AKS); (2) the substantial costs and burdens for the United States if the *qui tam* actions were to continue; (3) certain policy interests of Medicare and other federal healthcare programs; and (4) the investigative methods employed by "National Healthcare Analysis Group."

6. Following the teleconference on October 9, 2018, counsel for Venari Partners LLC and the NHCA Group Relators requested an opportunity to meet with the Department of Justice to further discuss the concerns identified by Mr. Granston. The Department again deferred filing any motions to dismiss and agreed to meet with relators' counsel on October 18, 2018, in Washington, D.C.

7. On October 18, 2018, a meeting was conducted at the offices of the Department of Justice in Washington, D.C., and the following individuals participated on behalf of NHCA Group and its affiliated relators:

Marc Mukasey, Greenberg Traurig LLP
Samuel Baxter, McKool Smith PC
Jennifer Truelove, McKool Smith PC
Radu Lelutia, McKool Smith PC
Rick Halper, McKool Smith PC
Jonathan Wilkerson, The Lanier Firm
Christopher Gadoury, The Lanier Firm
Bradford Geyer, Geyer Gorey LLP
John Mininno, Venari Partners LLC
Laura Gerber, Keller Rohrback, LLP (by telephone)
Brian Tipton, Florio Perrucci Steinhardt & Capelli, LLC (by telephone)
Gregory Spizer, Anapol Weiss (by telephone)
Richard Burke, Quantum Legal LLC (by telephone)
Zachary Jacobs, Quantum Legal LLC (by telephone)
Leslie Pescia, Beasley Allen PC (by telephone)
Lance Gould, Beasley Allen PC (by telephone)
Robert Connelly, Geyer Gorey LLP (by telephone)

Messrs. Raab and Granston, along with myself, attended the meeting on behalf of the Department of Justice. The meeting lasted approximately 90 minutes, during which relators' counsel made a power point presentation and provided supplemental documents relating to their allegations.

8. During the meeting on October 18, 2018, the parties discussed the topics identified by Mr. Granston on October 9, 2018. The parties also discussed the AKS, certain

regulatory safe harbors, and industry guidance promulgated by the United States Department of Health and Human Services, Office of Inspector General (HHS-OIG), including guidance pertaining to reimbursement and product support services.

9. On October 26, 2018, the Department of Justice received a letter, addressed to Mr. Granston, from Messrs. Baxter, Lanier, and Starr. In the letter, they stated that they were “grateful that [the Department] took the time to meet with us, and very much appreciate our discussion concerning the specifics and merits of Relators’ allegations.” The letter provided additional information relating to numerous topics discussed at the October 18, 2018 meeting.

10. On October 31, 2018, the Department of Justice received a letter, addressed to Joseph Hunt, Assistant Attorney General of the Civil Division of the Department of Justice, from Messrs. Baxter, Lanier, and Starr. In the letter they expressed their “gratitude” for the meeting on October 18, 2018, and requested that the Department continue discussions with relators’ counsel.

11. Following the correspondence of October 31, 2018, the Department again deferred filing any motions to dismiss so that relators could continue their discussions with the Department, and a conference call was scheduled for November 6, 2018.

12. On November 6, 2018, Department of Justice attorneys participated in a teleconference with counsel for certain of the NHCA Group Relators, including the following individuals:

Samuel Baxter, McKool Smith PC
Jennifer Truelove, McKool Smith PC
Radu Lelutia, McKool Smith PC
Kenneth Starr, The Lanier Firm
Christopher Gadoury, The Lanier Firm

The following Department of Justice attorneys participated in the teleconference: Assistant Attorney General Joseph Hunt; Stephen Cox, a Deputy Associate Attorney General; Messrs. Raab and Granston; and myself. The teleconference lasted approximately 60 minutes.

13. During the teleconference on November 6, 2018, the parties further discussed the topics identified by Mr. Granston on October 9, 2018. The parties also discussed AKS-related topics and related industry guidance promulgated by HHS-OIG, including, among other things, Department of Health and Human Services, OIG Advisory Opinion No. 11-08, at 6 (Jun. 14, 2011).

14. During the teleconference on November 6, counsel for the NHCA Group Relators stated that they had recently identified additional documents that they believed supported their allegations against certain defendants in cases pending outside Illinois, and the Department requested that they provide the documents after the teleconference.

15. On November 8, 2018, Mr. Lelutiu provided the Department with the documents referenced during the November 6, 2018 teleconference. No additional information was provided regarding the action filed by CIMZNHCA, LLC. Following receipt of the materials, the Department again deferred filing any motions to dismiss so that the materials could be reviewed.

16. On November 13, 2018, Messrs. Baxter, Lanier, and Starr sent a letter to the Department, addressed to Assistant Attorney General Joseph Hunt, in which they thanked the Department for its “commitment to consider [their] position fairly.” The letter was sent to “follow up on a number of issues ... discussed during the November 6 teleconference.” Among other things, the letter provided a further substantive responses concerning certain AKS-related topics and industry guidance promulgated by HHS-OIG.

17. On November 20, 2018, Mr. Granston emailed Mr. Lelutiu and requested that relators provide by November 30, 2018, any additional documents or information that they wanted the Department to consider. To inform their judgment regarding what, if any, information to send, Mr. Granston provided specific example topics.

18. On November 28, 2018, Mr. Starr sent a letter to the Department, addressed to Mr. Granston, that, among other things, requested “the opportunity to meet with appropriate OIG officials to discuss fully and fairly that Office’s understanding of the False Claims Act and Anti-Kickback Statute....” The United States did not make OIG officials available to discuss their understanding of these legal topics.

19. On November 29, 2018, Messrs. Baxter, Lanier, and Starr sent a letter to the Department, addressed to Assistant Attorney General Joseph Hunt. The letter, among other things, supplemented their response concerning a topic discussed at the October 18, 2018 meeting, specifically, the costs and burdens associated with continued litigation.

20. On November 30, 2018, Mr. Baxter sent a letter to the Department, addressed to Mr. Granston, which purported to respond to the information requests made on November 20, 2018. The letter provided relators’ response on a variety of legal and evidentiary issues, and discussed certain documents and information offered by relators in support of their allegations against certain defendants in cases pending outside Illinois. No additional information was provided regarding the action filed by CIMZNHCA, LLC.

21. On December 11, 2018, Mr. Starr sent a letter to the Department, addressed to The Honorable Noel Francisco, Solicitor General of the United States. The letter discussed relators’ views concerning their “active dialogue with the leadership and staff of the [Civil] Division.”

22. On December 17, Mr. Granston sent a letter to relators' counsel thanking them for the information that they had provided over the preceding two months and advising them that, based on the Department's investigations conducted over the preceding two years, including review of the supplemental information provided by relators, the Department planned to proceed with filing motions to dismiss pursuant to 31 U.S.C. § 3730(c)(2)(A).

23. Attached as Exhibit 1 is a true and correct copy of a settlement agreement dated January 25, 2019, pertaining to *United States ex rel. Doe v. Novo Nordisk, Inc., et al.*, No. 17-cv-791 (D.D.C.).

I declare under penalty of perjury that the foregoing is true and correct. Executed this 29th day of April, 2019.


Colin M. Huntley

EXHIBIT

1

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the following: Kathleen Gratton and Raymond Hippolyte ("Relators"); Relators' authorized representatives The Weiser Law Firm, P.C., and Simmer Law Group, PLLC (collectively "Relators' counsel"); and Precision Medicine Group, Inc., Precision for Medicine Holdings, Inc., Precision Effect, Inc. f/k/a Healthstar Educational Systems, Inc., d/b/a Practice Therapeutics (collectively, "Defendants"), through their authorized representatives. Collectively, Relators and Defendants will be referred to herein as "the Parties."

RECITALS

A. On or about February 22, 2016, Relators filed under seal a *qui tam* action in the United States District Court for the Northern District of Texas captioned *United States et al. ex rel. Jane Doe and John Doe v. Novo Nordisk, Inc., Practice Therapeutics, and Healthstar Communications*, Case No. 3:16-cv-00486-L (N.D. Tex.), pursuant to the *qui tam* provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3730(b) (the "Complaint"). On or about April 28, 2017, the Complaint was transferred under seal to the United States District Court for the District of Columbia and in that court was assigned the docket number 1:17-cv-00791-RBW. On or about July 27, 2017, the United States filed a notice with the Court that it was partially intervening in the Complaint as to certain claims asserted against Novo Nordisk, Inc., and "decline[d] intervention . . . as to all claims against Practice Therapeutics and Healthstar Communications asserted on behalf of the United States in this action." (Dkt. No. 24).

B. On or about January 5, 2018, Relators filed an amended complaint, naming each of the Defendants (as defined above) (the "FAC" and together with the Complaint, the "Action"). The Action alleges that Defendants caused the submission of false claims to federal healthcare programs (including Medicare, Medicaid and Tricare), by engaging in an illegal marketing and kickback scheme in connection with certain Novo Nordisk drugs (the "Drugs"). Specifically, the Action alleges that Defendants caused clinical educators, under the guise of providing disease-state and product education, to promote the Drugs or provide remuneration to patients or prescribers in order to induce prescriptions of such Drugs, in violation of the FCA and analogous State laws, as triggered by alleged violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-

7b(b)(2) dating from January 1, 2007 to the present. The conduct described in this paragraph will be referred herein to as "Relators' Claims." Defendants deny Relators' Claims and all liability in this matter.

C. Relators do not assert and expressly waive any claim that Defendants violated the retaliation provisions of the FCA at 31 U.S.C. § 3730(h).

D. This Agreement fully resolves Relators' Claims. This Agreement also resolves any claims of Relators and Relators' counsel pursuant to 31 U.S.C. § 3730(d) for expenses, attorney's fees, and costs arising from the filing of or in connection with the Action.

E. This Agreement is without prejudice to the rights, claims or responsibilities of the United States. The Parties understand and agree that the United States is providing no release to Defendants in connection with this Agreement, including without limitation any release of claims relating to Relator's Claims, claims arising from the Internal Revenue Code, or potential suspension or debarment action, or any administrative liability, including mandatory or permissive exclusion from Federal Health Care Programs.

F. This Agreement is not an admission of liability or of any fact by Defendants, or their present or former officers, directors, employees, shareholders, agents, parents, subsidiaries, or affiliates.

G. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the claims against the Defendants set forth in the Action, the Parties reach a full and final settlement, which they agree is fair and reasonable, in consideration of the sums to be paid as set forth in this Agreement.

TERMS AND CONDITIONS

1. Defendants shall pay to the United States and the Medicaid Participating States, collectively a total of Three Hundred and Fifty Thousand Dollars (\$350,000.00) to resolve the Relators' FCA Claims (the "FCA Settlement Amount").

A. Defendants shall pay to the United States the sum of \$325,010 no later than fifteen days after the Effective Date of this Agreement by electronic funds transfer

pursuant to written instructions to be provided by the United States Attorney's Office for the District of Columbia.

B. Defendants shall pay to the Medicaid Participating States the sum of \$24,990 no later than fifteen days after the Effective Date of this Agreement. The Medicaid State Settlement Amount shall be paid pursuant to written instructions from the NAMFCU Negotiating Team.

2. Relators acknowledge and agree that Defendants are in no way obligated or responsible for any payment of any statutory relator share of the FCA Settlement Amount that may be due to Relators.

3. No later than fifteen (15) business days after the Effective Date of this Agreement and after timely receipt of written instructions from Relators, Defendants shall pay Seventy-Five Thousand Dollars (\$75,000.00) pursuant to 31 U.S.C. § 3730(d) for expenses, attorney's fees, and costs arising from the filing of or in connection with the Action by electronic funds transfer to Relators' counsel, The Weiser Firm, P.C.

4. In consideration of the obligations of Defendants pursuant to this Agreement, and conditioned upon Defendants' full payment of the amounts described in Paragraphs 1 and 3 above and subject to Recital Paragraph E above, Relators agree for themselves, and for their heirs, successors, attorneys, agents, and assigns, to dismiss this Action with prejudice against Defendants and to release Defendants, including their current and former parents, subsidiaries, and affiliates, and their respective directors, officers, current and former employees, agents, and attorneys, and the predecessors, successors and assigns of each of the foregoing from any civil monetary claim the Relators had or may have had on their own behalf or on behalf of the United States or the States for: (1) Relators' Claims as described in Recital B above; (2) any claim for retaliation under 31 U.S.C. § 3730(h) or analogous State laws; (3) any claim under 31 U.S.C. § 3730(d) or analogous State laws, for expenses, attorney's fees, and costs; and (4) for any other claims known or unknown that the Relators, in their individual capacities, had or may have had against any of the Defendants including any and all causes of action, in law or in equity, suits, debts, liens, liability, obligations, claims, demands, *qui tam* relator shares, rights of subrogation, contribution and indemnity, damages, loss, cost or expenses, direct or indirect, of any kind or

nature whatsoever, whether known prior to the Effective Date of this Agreement or known after the Effective Date for this Agreement, fixed or contingent, state or federal, under common law, statute or regulation, liquidated or unliquidated, claimed or concealed, including, but not limited to, any claims arising in whole or in part from the Action, the matters alleged in the Action, the settlement of the Action, or the investigation and defense of the Action.

5. In consideration of the obligations of Relators pursuant to this Agreement, and conditioned upon the entry of the Joint Stipulation of Dismissal of this Action pursuant to Rule 41(a)(1) by the Court, Defendants agree to release Relators, their heirs, successors, attorneys, agents, and assigns, from any and all claims, known or unknown that Defendants have or may have had against the Relators, including any and all causes of action, in law or in equity, suits, debts, liens, liability, obligations, claims, demands, rights of subrogation, contribution and indemnity, damages, loss, cost or expenses, direct or indirect, of any kind or nature whatsoever, whether known prior to the Effective Date of this Agreement or known after the Effective Date for this Agreement, fixed or contingent, state or federal, under common law, statute or regulation, liquidated or unliquidated, claimed or concealed, including, but not limited to, any claims arising in whole or in part from the Action, the matters alleged in the Action, the settlement of the Action, or the investigation and defense of the Action.

6. In consideration of the obligations of Defendants pursuant to this Agreement, and conditioned upon Defendants' full payment of the amounts described in Paragraphs 1 and 3 above, Relators' counsel agree for themselves and for their respective law firms, and for their heirs, successors, attorneys, agents, and assigns, to release Defendants, including their current and former parents, subsidiaries, and affiliates, and their respective directors, officers, current and former employees, agents, and attorneys, and the predecessors, successors and assigns of each of the foregoing from any civil monetary claim that Relators' counsel had or may have had for any claim for attorney's fees and costs under 31 U.S.C. § 3730(d) or analogous State laws.

7. Defendants understand and agree that all costs and expenses incurred by or on behalf of the Defendants in connection with the defense, investigation into, or settlement of this Action or negotiation, performance or payment under this Agreement are unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205.47; and in Titles XVIII and

XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting purposes and may not be charged, directly or indirectly, to the United States, Medicare, Medicaid, TRICARE, or FEHBP or any State Medicaid program.

8. Defendants agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon Relators' Claims.

9. Relators and Defendants agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

10. This Agreement is intended to be for the benefit of the Parties only.

11. Within five (5) business days of receipt of the payments described in Paragraphs 1 and 3, Defendants and Relators shall submit a Joint Stipulation of Dismissal of this Action pursuant to Rule 41(a)(1). Dismissal of this Action will be with prejudice as to Relators. Dismissal of this Action will be without prejudice as to the United States and the Medicaid Participating States.

12. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

13. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

14. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of New Jersey. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by both Parties to this Agreement and shall not, therefore, be construed against either Party for that reason in any subsequent dispute.

15. This Agreement and the Side Agreement entered into concurrently with this Agreement constitute the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

16. The undersigned counsel represents and warrants that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

17. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.


18. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles or electronic mail versions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

* * * * * END * * * * *

DATED:

Jan 22, 2019


Defendants



John Mariano, Senior Vice President and General
Counsel
Precision Medicine Group, Inc., Precision for
Medicine Holdings, Inc., Precision Effect, Inc. f/k/a
Healthstar Educational Systems, Inc., d/b/a Practice
Therapeutics

DATED:

1/22/19



Rebecca C. Martin
Andrew B. Kratenstein
McDermott Will & Emery LLP
Counsel to Precision Medicine Group, Inc.,
Precision for Medicine Holdings, Inc., Precision
Effect, Inc. f/k/a Healthstar Educational Systems,
Inc., d/b/a Practice Therapeutics

Relators

DATED

:

Kathleen Gratton
Relator

DATED

:

Raymond Hippolyte
Relator

DATED

:

8/17/2019



Christopher Nelson
The Weiser Law Firm, P.C.
Counsel to Relators Kathleen Gratton and
Raymond Hippolyte

DATED

:

Scott Simmer
Simmer Law Group PLLC
Counsel to Relators Kathleen Gratton and
Raymond Hippolyte

Relators

DATED
:

1-8-2019

Kathleen Gratton

Kathleen Gratton
Relator

DATED
:

-

Raymond Hippolyte
Relator

DATED
:

Christopher Nelson
The Weiser Law Firm, P.C.
Counsel to Relators Kathleen Gratton and
Raymond Hippolyte

DATED
:

Scott Simmer
Simmer Law Group PLLC
Counsel to Relators Kathleen Gratton and
Raymond Hippolyte

Relators

DATED

:

Kathleen Gratton
Relator

DATED

:

1/8/2019


Raymond Hippolyte
Relator

DATED

:

Christopher Nelson
The Weiser Law Firm, P.C.
Counsel to Relators Kathleen Gratton and
Raymond Hippolyte

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Scott Simmer
Simmer Law Group PLLC
Counsel to Relators Kathleen Gratton and
Raymond Hippolyte

Relators

DATED

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Kathleen Gratton
Relator

DATED

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Raymond Hippolyte
Relator

DATED

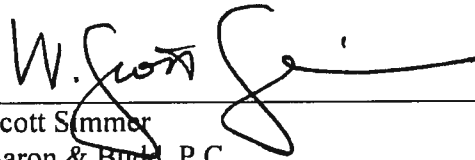
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Christopher Nelson
The Weiser Law Firm, P.C.
Counsel to Relators Kathleen Gratton and
Raymond Hippolyte

DATED

:

1/25/2019



Scott Summer
Baron & Budd, P.C.
Counsel to Relators Kathleen Gratton and
Raymond Hippolyte